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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/304,121	05/03/99	VOELLMY	R 870109.409

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EXAMINER

WINKLER, U

ART UNIT

PAPER NUMBER

1648

*19*

DATE MAILED:

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/304,121

Applicant(s)

VOELLMY, RICHARD

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-33 and 35-37 is/are allowed <sup>able</sup>.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-8 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

### DETAILED ACTION

The Amendment filed 12 April 2001 (Paper No. 17) in response to the Office Action of 19 December 2000 is acknowledged and has been entered. Claims 1-33 and 35-37 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claims 1 under 35 U.S.C. 102(b) as being anticipated by Moonen Chrit (WO 98/06864) is **maintained**. Applicant's arguments filed 12 April have been fully considered but they are not persuasive. Applicant argues that the heat shock factors are not heat-regulated in all organisms. The reference cited by applicant to support this assertion (Sarge et al., Genes and Development, 1991) discloses that, at least in the mouse, there is one heat shock factor that is indeed heat-regulated. Moonen Chrit discloses activating endogenous heat shock genes in a mouse, which has been transformed with an adenoviral vector. The reference discloses a therapeutic gene under the control of a heat shock promoter. The therapeutic gene and heat-shock promoter combination is interpreted as the second nucleic acid molecule while the first nucleic acid molecule is interpreted to be the endogenously present heat shock promoter and heat shock transcription factor. Therefore, the instant invention is anticipated by Moonen Chrit.

This rejection can be overcome by amending the claim to indicate that the nucleic acid of the molecular circuit must be inserted into the cell. Applicant is reminded that any amendment to the claims must be supported by the specification in order to avoid a written description rejection.

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The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicant's arguments and the declaration..

The rejection of claims 1-33 and 35 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is withdrawn** in view of applicant's declaration.

The rejection of claims 1-33 and 35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a molecular circuit that utilizes the hsp70 stress promoter and a portion of the RNA leader sequence of the human *hsp70B* gene, operably linked to a gene, in this instance luciferase, and a *hsp70B*-mutated HSF1 gene operably linked to a promoter, does not reasonably provide enablement for all promoters and transcription factors **is withdrawn** in view of applicant's declaration.

Claims 2-8 objected to because of the following informalities: They are dependent on a rejected claim. Appropriate correction is required.

### ***Conclusion***

Claim 1 is rejected.

Claims 2-8 are objected to.

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Claims 2-33 and 35-37 are allowable.

This application contains claim 34 drawn to an invention nonelected in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
JEFFREY STUCKER  
PRIMARY EXAMINER